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10/711,155	08/27/2004	Bryan E. GARNER	5233.012.NPUS00	5154

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EXAMINER	
SHAW, AMANDA MARIE	
ART UNIT	PAPER NUMBER
1634	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/711,155	GARNER, BRYAN E.	
	Examiner	Art Unit	
	AMANDA SHAW	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,7,9-15 and 37-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,7,9-15 and 37-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 August 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/31/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the amendment filed December 31, 2007. This action is made non final.

Claims 1-3, 7, and 9-15, and 37-41 are currently pending and have been addressed herein. Claims 9 and 12 have been amended.

Withdrawn Objections

2. The objections made in section 4 of the Office Action of August 29, 2007 are withdrawn in view of amendments made to the claims.

Withdrawn Rejections

3. The rejections made under 35 USC 103(a) in sections 6-9 of the Office Action of August 29, 2007 are withdrawn in view of the Applicants arguments on pages 2-5 in the response filed December 31, 2007. The Applicants main argument is that Yamamoto specifically excludes an incubation step with MPN is combined with PCR.

Specification

4. The disclosure is objected to because the first paragraph of the disclosure refers to Disclosure Document No 529733, received April 15, 2003, entitled "Analyzing Probiotics in Animal Feed". The Applicants are reminded that the first paragraph of the disclosure should only refer to prior filed applications that are claiming benefit under 35 USC 120, 121, 365(c) or 119(e). See MPEP 201.11. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7and 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7 recites the limitation "said at least one oligonucleotide". There is insufficient antecedent basis for this limitation in the claim because the claims do not previously refer to “at least one oligonucleotide”.

Claims 7 and 9 recite the limitation "the specific kind of microorganism". First of all there is insufficient antecedent basis for this limitation in the claim because the claims do not previously refer to a “specific kind of organism”. Additionally it is unclear what a "specific kind of microorganism" refers to. For example it is unclear if it refers to a specific genus of microorganisms or a specific species of microorganisms

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1, 9-13, and 15 are rejected under 35 U.S.C. 103(a) as being obvious over Miwa (J. Vet. Med. Sci. 1997) in view of Mantynen (International Journal of Food Microbiology 1997) and in further view of Racioppi (US Patent 5702944 Issued 12/1997).

Miwa teaches using the most probable number method combined with nested PCR for the detection and enumeration of bacteria in the intestinal contents of cattle, pig and chicken. Ten fold serial dilutions of samples were added to three tubes of enrichment medium, which were incubated at 37ºC for 20-24 hours and then analyzed by PCR analysis (Abstract). Thus Miwa teaches a method comprising obtaining a liquid suspension sample comprising a viable microorganism, preparing a series of progressively dilute test samples, incubating the series of progressively dilute test samples, conducing PCR analysis on the series of progressively dilute test samples, and using the most probable number model to determine the concentration of viable microorganism in the sample as required by claim 1. Miwa teaches that ten fold serial dilutions of samples were added to three tubes of enrichment medium, which were incubated at 37ºC for 20-24 hours and then analyzed by PCR analysis (Abstract). Thus Miwa teaches a method wherein the samples were prepared by dividing the sample into multiple portions (i.e. three test tubes) and incubating each portion wherein the microorganism was detected in each portion as required by claim 9. Further Miwa teaches a method wherein the samples were diluted and then divided into multiple samples (i.e. 3 test tubes) as required by claim 10. Additionally Miwa teaches a method

wherein the samples were diluted by mixing the sample with a liquid to produce a fluid mixture and then dividing the fluid mixture into multiple samples (i.e. 3 test tubes) as required by claim 11.

Miwa does not teach a method wherein the sample is obtained from a microbially treated food product. Miwa does not teach a method wherein the sample is obtained from a food product. Additionally Miwa does not exemplify using at least one oligonucleotide and detecting the presence or absence of a product of hybridization as required by claim 12. Further Miwa does not exemplify using two oligonucleotide primers to detect the presence or absence of a product of the PCR reaction as required by claim 13. Miwa does not exemplify a method wherein the detecting of the presence or absence of a product includes performing electrophoresis as required by claim 15.

However Mantynen teaches a method which utilizes a most probable number PCR assay for detection and enumeration of enterotoxin C producing Staphylococcus aureus from fresh cheese (Abstract). Mantynen teaches that S. aureus was grown and a known amount was added to 1 liter of milk. The milk was then used to make fresh cheese (Page 136, column 2 to Page 137, column 1). Thus Mantynen teaches a method wherein the sample is obtained from a microbially treated food product. Mantynen teaches that for enumeration of S. aureus from cheese, ten fold dilution series from all of the samples were prepared and subjected to PCR. Mantynen teaches that two PCR primers that are specific for the detection of the entC1 gene of S. aureus were used to amplify the DNA. These oligonucleotide primers hybridize to the nucleic acid sequence that is being detected and serve as a starting point for DNA amplification

(Page 138, Column 2). Therefore Mantynen teach a method of using at least one oligonucleotide to detecting the presence or absence of a product of hybridization as required by claim 12 since if the primers cannot hybridize to the target a PCR product is not formed. Mantynen further teaches that they were able to detect a 801 bp fragment of the entC1 gene using primers 1 and 2 and they were also able to detect a 631 bp fragment of the entC1 gene using primers 3 and 4 (Fig 1). Thus Mantynen teaches using two oligonucleotide primers to detect the presence or absence of a product of the PCR reaction as required by claim 13. Mantynen teaches a method wherein the detecting of the presence or absence of a product includes performing electrophoresis as required by claim 15 (Fig 1).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have applied the method of Miwa to the detection of microorganisms that are present in food products as suggested by Mantynen. Particularly Mantynen teaches that certain Staphylococcus aureus strains produce heat stable enterotoxins which can cause food poisoning. Therefore one would have been motivated to use the method of Miwa to quantify microorganisms such as S. aureus in food samples in order to make sure the food product will not cause food poisoning.

Additionally regarding claim 1 Miwa does not teach a method wherein the microorganisms are suspended in a liquid recovery media.

However Racioppi teaches a method wherein once a microbial sample has been collected the sample is placed a specialized transport media while the sample is transported to the clinical or diagnostic laboratory (Column 1, lines 10-40). Racioppi

further teaches that the specialized transport media supports the viability of the microorganism of interest while hindering the growth of other microorganisms in the sample (Column 4, lines 40-52).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Miwa and Mantynen by placing the sample in a liquid recovery media as suggested by Racioppi. Liquid recovery medias also commonly referred to as transport medias were well known in the art at the time of the invention as demonstrated by Racioppi and thus it would have been obvious to an ordinary artisan to have placed a sample in a recovery media while transporting the sample to a laboratory particularly since transport medias can be designed to support the viability of the microorganism of interest while hindering the growth of other organisms which are present in the sample and may contaminate the sample (Column 4, lines 40-52).

8. Claims 2-3 and 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miwa (J. Vet. Med. Sci. 1997) in view of Mantynen (International Journal of Food Microbiology 1997) and Racioppi (US Patent 5702944 Issued 12/1997) as applied to claim 1 above and in further view of Ware (US Patent 5534271 Issued 1996).

The teachings of Miwa, Mantynen, and Racioppi are presented above.

Regarding Claims 2-3 the combined references do not teach a method wherein the sample being tested is a sample of animal feed that was taken from a feed pile and transported to a testing lab in way so that the sample at the lab is representative of the

condition of the animal feed when the animal feed is to be consumed by animals. Further the references do not teach a method wherein the sample of animal feed is taken from a feed pile at a location where the animal feed is to be consumed by animals.

However, Ware et al teaches a method wherein bacteria cultures of Lactobacillus acidophilus and Propionibacterium P-5 are admixed with an animal feedlot diet to counter the effects of acidosis brought about by a transition from a roughage dies to a high grain diet. In Example IV Ware teaches that they tested the stability of L. acidophilus and its ability to survive on feed that is being fed to steers. The testing was performed at the Silliker Laboratories in Chicago. Ware et al does not exemplify that the samples are taken from a feed pile at a location where the animal feed is to be consumed and transported to a lab in a way that the sample is representative of the condition of animal feed when the animal feed is to be consumed, however it would be obvious to have tested the sample under the same conditions of the animal feed when it is feed to animals particularly because Ware et al teaches that L acidophilus is a very sensitive organism that is difficult to maintain in a viable state at ambient temperatures. Any shift in the temperature during the transportation of the sample from the animal feedlot to the laboratory could potentially kill the L. acidophilus during transportation thus yielding invalid results (Column 11, lines 33-67). For these reasons it would be obvious to transport the animal feed from the feedlot under the same conditions of the animal feed when it is feed to animals.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Miwa, Mantynen, and Racioppi by taking a sample of animal feed to a laboratory in order to perform testing wherein the sample is transported to the lab in a way that the sample is representative of the condition of animal feed when the animal feed is to be consumed as suggested by Ware. The benefit of performing the testing in a lab opposed to at the animal feed lot is that it reduces contamination, particularly since both Microbiology and Molecular biology assays are very sensitive and can be contaminated easily. The benefit of transporting the samples from the feedlot to the lab in a way that the sample is representative of the condition of animal feed when the animal feed is to be consumed is that if the conditions change it could compromise the sample particularly since Ware teaches that L. acidophilus is very sensitive.

Regarding Claims 37-40 the combined references do not teach a method wherein the microorganism of interest is a probiotic organism, wherein the probiotic microorganism is a species of Lactobacillus, particularly L. acidophilus.

However Ware et al teach a method for detecting Lactobacillus acidophilus and Propionibacterium P-5 found in animal feed (Column 11, lines 33-66).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the method of Miwa, Mantynen, and Racioppi to detect and quantify the amount of a probiotic such as Lactobacillus that was applied to animal feed as suggested by Ware. Probiotics such as Lactobacillus are routinely added to animal feed to increase milk and meat production. It would be

beneficial to quantitate the amount of L. acidophilus is animal feed because Ware et al have shown that the amount of the probiotic in animal feed can change depending on the storage conditions (Column 11, lines 22-66).

9. Claims 7 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miwa (J. Vet. Med. Sci. 1997) in view of Mantynen (International Journal of Food Microbiology 1997) and Racioppi (US Patent 5702944 Issued 12/1997) as applied to claims 1 and 13 above and in further view of Lucchini (Federation of European Microbiological Societies 1998).

The teachings of Miwa, Mantynen, and Racioppi, are presented above.

The combined references do not teach a method wherein one PCR primer hybridizes with a nucleic acid sequence indicative of the genus of the specific kind of microorganism, and another of the PCR primers hybridizes with a nucleic acid sequence indicative of the species of the specific kind of microorganism.

However Lucchini et al teach a method wherein multiplex PCR was performed using four oligonucleotide primers. Two genus specific primers named LARNA5 and LARNA6 were used. These primers were specific to a conserved region of 248 bp within the 16S rRNA gene of lactobacilli. Two species-specific primers named APF3 and APF4 were also used. These primers were specific to L. gasseri (Page 274, column 2).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Miwa, Mantynen, and

Racioppi so as to have used one PCR primer which hybridizes with a nucleic acid sequence indicative of the genus of the specific kind of microorganism, and another of the PCR primers hybridizes with a nucleic acid sequence indicative of the species of the specific kind of microorganism for the added benefit of being able to distinguish between different species when more than one species is suspected of being present in the sample to be tested.

10. Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miwa (J. Vet. Med. Sci. 1997) in view of Mantynen (International Journal of Food Microbiology 1997), Racioppi (US Patent 5702944 Issued 12/1997), and Ware (US Patent 5534271 Issued 1996) as applied to claims 1, 37, and 38 above, and in further view of Rust et al (Cattle Call 2000).

The teachings of Miwa, Mantynen, Racioppi, and Ware are presented above.

The combined references do not teach a method wherein the microorganism of interest is Lactobacillus LA-51.

However Rust et al teach that strain LA51 of Lactobacillus acidophilus can be added to animal feed. The addition of LA51 has been shown to help improve carcass adjusted average daily gain and feed conversion efficiency (Summary).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have further modified the methods of Miwa, Mantynen, Racioppi, and Ware by additionally assaying for Lactobacillus LA51 in animal feed

because it is an important microorganism that is routinely added to animal feed to improve carcass adjusted average daily gain and feed conversion efficiency.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In *re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 7, 9-15, and 37-40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 and 16-17 of copending Application No. 10/711,156 in view of Ware and Rust. Although the conflicting claims are not identical, they are not patentably distinct from each other. Both the present claims and the claims of '156 encompass methods for quantifying the presence of a microorganism in a sample of food. The present claims differ from the claims of '156 in that the claims of '156 do not recite that the microorganism being

detected is Lactobacillus, L. acidophilus, or Lactobacillus LA51 in samples of animal feed that are transported from an animal feedlot to a laboratory for culturing and using an oligonucleotide to detect the microorganism. However, Ware teaches a method for detecting L. acidophilus in steer food. The test samples were taken from steer food and the testing was performed at the Silliker Laboratories in Chicago, IL (Column 11). Ware et al does not exemplify that the samples are taken from a feed pile at a location where the animal feed is to be consumed, however it would be obvious to one of ordinary skill in the art at the time the invention was made to have tested the sample under the same conditions of the animal feed when it is feed to animals because Ware et al teaches that L acidophilus is a very sensitive organism that is difficult to maintain in a viable state at ambient temperatures. Any shift in the temperature during the transportation of the sample from the animal feedlot to the laboratory could potentially kill the L. acidophilus during transportation thus yielding invalid results. Additionally Rust et al teach that strain LA51 of Lactobacillus acidophilus can be added to animal feed. The addition of LA51 has been shown to help improve carcass adjusted average daily gain and feed conversion efficiency (Summary). Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to detect and quantify Lactobacillus LA51 in animal feed because it is an important microorganism that is routinely added to animal feed to improve carcass adjusted average daily gain and feed conversion efficiency.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

RESPONSE TO ARGUMENTS

12. In the response filed December 31, 2007, Applicants stated that pending client documentation a terminal disclaimer will be filed to overcome the non statutory double patenting rejection. As of the date that this Office Action was created the Office has not yet received the terminal disclaimer. Accordingly, the rejection is maintained.

Conclusion

13. No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMANDA SHAW whose telephone number is (571)272-8668. The examiner can normally be reached on Mon-Fri 7:30 TO 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amanda M. Shaw
Examiner
Art Unit 1634

/Juliet C Switzer/

Primary Examiner, Art Unit 1634